Medicinal products for human use: Community code. Codification

1999/0134(COD) - 25/06/2003 - Implementing legislative act

COMMUNITY MEASURE : Commission directive 2003/63/EC amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use. CONTENT : the detailed scientific and technical requirements of Annex I to Directive 2001/83/EC need to be adapted to take account of scientific and technical progress and in particular of a large set of new requirements resulting from recent legislation. The presentation and content of the marketing authorisation application dossier have to be improved in order to facilitate the assessment and the better use of certain parts of the dossier which are common to several medicinal products. It is appropriate to establish a new system aimed at simplifying procedures for both the approval of and subsequent changes to human plasma-derived medicinal products. The standardised marketing authorisation dossier requirements (harmonised format) should be applicable to any type of medicinal product for human use, regardless of the procedure for the granting of the marketing authorisation. Some medicinal products present, however, such specific features that all the requirements cannot be fulfilled. To take account of these particular situations, a simplified dossier presentation should be provided for. To this end the concept of a plasma master file (PMF) should be introduced, in particular in order to allow the pooling of national expertise and through the coordination by the EMEA of a single evaluation. A PMF should serve as a stand-alone document, which is separate from the marketing authorisation dossier and through which a harmonised control of the relevant information regarding starting material used for the manufacture of plasma-derived medicinal products could be achieved. The PMF system should consist of a two-step assessment: first, an assessment of the PMF carried out at Community level, the result of which, i.e. a certificate of compliance with the Community legislation for each PMF, must be taken into account by any national competent authority, preventing them of any subsequent reassessment; second, an assessment of the finished plasma-derived medicinal product containing the modified part of the PMF (the two essential parts of the content, plasma origin and plasma quality-safety). This should remain the task of the competent authority that granted the marketing authorisation for the plasma-derived medicinal product. In the case of vaccines for human use, the same antigen may be common to several medicinal products (vaccines) and any change to that particular antigen, ipso facto, may impact, therefore, on several vaccines authorised by different procedures. In order to simplify the existing procedures for the assessment of such vaccines, both for the granting of a first marketing authorisation and for subsequent changes to it due to modifications to the manufacturing process and testing of individual antigens involved in combined vaccines, a new system based on the concept of a vaccine antigen master file (VAMF) should be introduced. This VAMF will allow the pooling of national expertise, and through the coordination by the EMEA, a single evaluation of the concerned vaccine antigen. The VAMF should serve as a stand-alone part of the marketing authorisation dossier and provide allrelevant information of a biological and chemical nature related to one specific antigen, which constitutes one of the active substances of one or several combined vaccines. The VAMF system should consist of a two-step assessment: first, an assessment of the VAMF carried out at Community level, the result of which, i.e. a certificate of compliance with the Community legislation for each VAMF, must be taken into account by any national competent authority, preventing them from any subsequent reassessment; second, an assessment of the finished medicinal product (combined vaccine) containing the modified antigen which is the task of the competent authority that granted the combined vaccine marketing authorisation. Herbal medicinal products differ substantially from conventional medicinal products in so far as they are intrinsically associated with the very particular notion of herbal substances and herbal preparations. It is therefore appropriate to determine specific requirements for herbal medicinal products with regard to the standardised marketing authorisation requirements. Lastly, the treatment of various acquired and inherited pathological dysfunctions in humans calls upon novel concept-based approaches based on the development of biotechnology techniques. The latter involve the use of advanced therapy medicinal

products based on processes focused on various gene-transfer-produced bio-molecules (gene therapy medicinal products) and manipulated or processed cells (cell therapy medicinal products) as active substances. The general principles already applicable to these products should be specified from a scientific and technical point of view and the specific requirements with regard to the standardised marketing authorisation requirements should be determined.